K072109
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RAMSEY
MEDICAL INC.

JUL 31 2008

510(k) SUMMARY

Date Prepared: 7/30/2007

Contact:

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Contact Person:

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Device Trade Name: statMAP Model 7200 Blood Pressure Measuring Device

Common Names: Blood Pressure Measuring Device, Blood Pressure Monitor

Classification Name: Non Invasive Blood Pressure Measurement System

Includes the following parameters:

Systolic Pressure
Diastolic Pressure
Mean Arterial Pressure
Heart Rate

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Classification

Classification Name	21 CFR Section	Product Code	Class
Non-Invasive Blood Pressure Measurement System	870.1130	DXN	2

Predicate Devices

Ramsey Medical, Inc., is claiming substantial equivalence to the following legally marketed device:

Aspect	Device	510(k) number
Non-invasive Blood Pressure	Critikon Model 8100 Vital Signs Monitor	K854434

Device Description

The statMAP Model 7200 Blood Pressure (BP) Measurement Device is a hand-held device designed to provide semi-automatic or manual Blood pressure measurement on Adults, Pediatrics and Neonates. The design concept for the statMAP Model 7200 is a small, very compact BP measurement device that combines both the totally manual measurement methods, such as the manual auscultatory and the palpatory methods, and automatic electronic non-invasive blood pressure (NIBP) measurement devices using the oscillometric method of BP determination.

The statMAP Model 7200 allows for two basic modes of NIBP measurement, which are manual NIBP measurement and semi-automatic NIBP measurement. The statMAP Model 7200 measurement modes are summarized as follows:

1) Semi-automatic NIBP Determination
In this mode, the device performs an electronic determination of Blood Pressure (using the oscillometric method) and Heart Rate. The user controls only the inflation of the limb compression cuff while the deflate rate of the cuff is performed automatically by the integrated deflate valve controlled by the statMAP Model 7200 electronics. The BP and HR values are displayed for the user as a set of illuminated LEDs at the edge of the dial face.

2) Manual BP determination

In this mode, the device functions as a palm style aneroid sphygmomanometer with an integral cuff inflation bulb and manual deflate valve. Blood pressures are determined by the operator using the traditional auscultatory method or the palpatory or the manual oscillometric mode.

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Intended Uses

The statMAP Model 7200 is designed for use in a variety of settings where Blood Pressure Measurement is required on Adults, Pediatrics, or Neonates: these include hospital departments such as intensive care units, medical/surgical nursing units, emergency department, labor and delivery, radiology, recovery, cardiac care units, and step-down units; statMAP Model 7200 is also designed for use in out-patient centers, physicians offices, the home, as well as EMS environments. The statMAP Model 7200 device will display Systolic, Diastolic, MAP and Heart Rate.

Comparison of Technological Characteristics

The statMAP Model 7200 and the predicate device share essentially the same intended use and technological characteristics.
Both devices employ the Oscillometric method of Blood Pressure Measurement and use an electronic deflate valve to step-deflate the cuff during the measurement cycle. Systolic, Diastolic, Mean Arterial Pressure, and Heart Rate are displayed.

The predicate device has a built-in pump for inflation whereas the statMAP Model 7200 relies on the user to manually inflate the cuff using its integrated inflation bulb. The statMAP Model 7200 also supports manual blood pressure measurement as a traditional aneroid sphygmomanometer.

The predicate device also has a programmable auto-cycling capability, while the statMAP is not designed for unattended operation.

Device testing

The statMAP Model 7200 has been comprehensively tested to demonstrate its performance, safety and efficacy, specifically:

- EN 60601-1 Safety – Medical Equipment
- IEC601-2-30 – Particular Requirements for Automatic Cycling NIBP monitors
- Mechanical Shock and Vibration – ISTA2A
- Electromagnetic Compatibility – EN60601-1-2
- Battery Testing
- Comparison testing between statMAP Model 7200 and Predicate Device
- Intra-device variability
- Environmental testing (Temperature and Humidity)

Conclusions

In accordance with 21 CFR part 807.92(b) (3) and as presented in the pre-market notification, Ramsey Medical, Inc., concludes that the new device, statMAP Model 7200 is safe, effective and substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2008

Ramsey Medical Inc.
c/o Mr. Darryl Parmet
Engineering Consultant
4920 West Cypress Street, Ste. 110
Tampa, FL 33607

Re: K072109
Trade/Device Name: statMAP Model 7200 Blood Pressure Measurement Device
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 26, 2008
Received: June 27, 2008

Dear Mr. Parmet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K072109**

Device Name: **statMAP Model 7200 Blood Pressure Measurement Device**

Indications For Use:

The statMAP Model 7200 Blood Pressure Measurement Device is a prescription device, and is indicated for use to measure systolic, diastolic, mean arterial pressure (MAP) and heart rate of persons ages 12 and over using the oscillometric method of measurement.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072109